510(k) Summary

Device Trade Name:	One-Piece PEEK Fusion Implant
Manufacturer:	MTP Solutions LLC 124 South 600 West, Suite 100 Logan, UT 84321
Contact:	Mr. Robert Hoy Director of Technical & Clinical Research Phone: (614) 448-6358 Fax: (435) 213-4878 bob@venturemd.com
Prepared by:	Musculoskeletal Clinical & Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 Phone: (202) 552-5800 Fax: (202) 552-5798
Date Prepared:	May 12, 2014
Common Name:	Screw, Fixation, Bone
Classification:	21 CFR 888.3040
Class:	II
Product Code:	HWC

Indications for Use:
The One-Piece PEEK Fusion Implant is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

Device Description:
The One-Piece PEEK Fusion Implant is manufactured from polyetheretherketone (PEEK). It is threaded on one end and ridged on the other to engage either side of an osteotomy or reconstruction site. The One-Piece PEEK Fusion Implant is threaded into the proximal phalanx and then it is press fit into the middle phalanx, allowing for reduction and fixation of the bone fragments.

Predicate Devices:
The One-Piece PEEK Fusion Implant is substantially equivalent to the MTP Solutions LLC PEEK Fusion Implant (K133515) and Arthrex Bio-Pin device (K050259) with respect to its indications for use, materials, dimensions, function and performance.

Technological Characteristics Comparison:
The One-Piece PEEK Fusion Implant and its predicate device are available in similar sizes and dimensions. In addition, both devices are designed to be deployed across osteotomy and reconstruction sites with the purpose of fixing bone fragments. Both the One-Piece PEEK Fusion Implant and PEEK Fusion Implant (K133515) are manufactured from polyetheretherketone (PEEK). The biocompatibility of the candidate device material and predicate device is further substantiated by the data available in MAF-1922.

Nonclinical Testing:
The device design was evaluated using the following verification tests, which are the same tests performed on the predicate device to establish its substantial equivalence in submission K133515:

- Tensile Strength
- Bending Strength
- Torsional Strength
- Fatigue Testing
- Post-Fatigue Tensile Strength

The results of this testing as summarized in the Design Control Activities Summary demonstrate that the One-Piece PEEK Fusion Implant met the pre-determined acceptance criteria for the verification activities. Therefore, the differences between the modified and predicate devices introduce no new issues of safety or effectiveness.

Conclusion:
The One-Piece PEEK Fusion Implant met all specified criteria performing as intended and did not raise any new issues of safety or effectiveness. The Indications/Intended Use and the fundamental scientific technology of the One-Piece PEEK Fusion Implant are identical to those described in the predicate device. The One-Piece PEEK Fusion Implant has been determined by MTP Solutions to be substantially equivalent to the PEEK Fusion Implant (K133515) and Arthrex Bio-Pin device (K050259).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2014

MTP Solutions LLC
Mr. Robert Hoy
Director of Technical & Clinical Research
124 South 600 West, Suite 100
Logan, Utah 84321

Re: K140970
Trade/Device Name: One-Piece PEEK Fusion Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 15, 2014
Received: April 16, 2014

Dear Mr. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K140970 (pg 1/1)

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Indications for Use:

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of _____

Elizabeth L. Frank -S

Division of Orthopedic Devices